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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,279	04/19/2007	Kerstin Ehler	Le A 36 810	9770

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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03/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,279

Applicant(s)

EHLERT ET AL.

Examiner

CHRISTIAN L. FRONDA

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. Claims 1-14 are pending in the instant application. Claims 5-8 stand withdrawn from further consideration as being drawn to a nonelected invention
2. Claims 1-4 and 9-14 are under consideration in this Office Action. New additional grounds of rejection are presented in the instant Office Action.
3. The objection to the title of the invention has been obviated by the amendment to the specification filed 12/03/2008.
4. The rejection of claims 1-4 under 35 USC 101 has been obviated by the amendment to the claims filed 12/03/2008.
5. The rejection of claim 4 under 35 U.S.C. 112, first paragraph, for failing to comply with the enablement requirement has been obviated by the amendment to the claims filed 12/03/2008.
6. The rejection of claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by Bhavsar et al. has been obviated by the amendment to the claims filed 12/03/2008.
7. The rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Bhavsar et al. in view of Kain et al. has been obviated by the amendment to the claims filed 12/03/2008.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the SEQ ID NO identifiers in parenthesis which renders the claims vague and indefinite. The metes and bounds of the claim are uncertain since it is unclear if the applicants actually intended to limit the claims to the sequences. Appropriate correction is requested.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

According to MPEP 2143:

“Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.”

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhavsar et al. (Appl Environ Microbiol. 2001 Jan;67(1):403-10; reference of record) in view of Kain et al. (Curr Protoc Mol Biol. 2001 May;Chapter 9: Unit9.6; reference of record) and Conrad et al. (Mol Gen Genet. 1996 Feb 5;250(2):230-6 (ABSTRACT); PTO 892).

Bhavsar et al. teach the plasmid pSWEET comprising the xylA promoter, ribosome binding site from *B. subtilis*, a reporter gene encoding a thermostable β -galactosidase reporter which is operably linked to the promoter, a selection marker for chloramphenicol, and an origin of replication. See entire publication especially pages 403-405 and Figs. 1-6. The teachings of the reference differ from the claims in that the plasmid pSWEET does not contain the luciferase reporter gene and the T7 promoter.

Conrad et al. teach a T7 promoter specific for gene expression in *B.subtilis* and an efficient protein expression system for *B.subtilis* using said T7 promoter.

Kain et al. teach the luciferase reporter gene, where luciferase is a widely used reporter enzyme which is much faster and more sensitive than the chloramphenicol acetyltransferase (CAT) assay and does not use radioactivity. See entire publication.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plasmid pSWEET of Bhavsar et al. such that the thermostable β -galactosidase reporter gene is replaced with the luciferase reporter gene taught by Kain et al. and the xylA promoter is replaced with the T7 promoter taught by Conrad et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to have a reporter system that can predictably be used in measuring gene expression, where luciferase is a widely used reporter enzyme which is much faster and more sensitive than the CAT assay and does not use radioactivity and the T7 promoter taught by Conrad et al. provides for efficient protein expression in *B.subtilis*. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because the art of molecular biology and recombinant DNA manipulation are well known and developed.

12. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhavsar et al. (Appl Environ Microbiol. 2001 Jan;67(1):403-10; reference of record) in view of Kain et al. (Curr Protoc Mol Biol. 2001 May;Chapter 9: Unit9.6; reference of record).

The teachings of Bhavsar et al. have been stated above. The teachings of the reference differ from the claims in that the plasmid pSWEET does not contain the luciferase reporter gene.

Kain et al. teach the luciferase reporter gene, where luciferase is a widely used reporter enzyme which is much faster and more sensitive than the chloramphenicol acetyltransferase (CAT) assay and does not use radioactivity. See entire publication.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plasmid pSWEET of Bhavsar et al. such that the thermostable β -galactosidase reporter gene is replaced with the luciferase reporter gene taught by Kain et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to have a reporter system that can predictably be used in measuring gene expression, where luciferase is a widely used reporter enzyme which is much faster and more

sensitive than the CAT assay and does not use radioactivity. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because the art of molecular biology and recombinant DNA manipulation are well known and developed.

Applicants' arguments filed 12/03/2008 have been fully considered but are not persuasive. Applicants have not provided evidence in a suitable declaration that contradicts, refutes, and discredits the operability of the combination of the reference teachings. Furthermore, the art of molecular biology and recombinant DNA manipulation are well known and well developed such that one of ordinary skill in the art at the time the invention was made would be able to produce a stable functioning construct that expresses the luciferase reporter.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Patent Examiner

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